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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,022	03/12/2004	Frederick F. VanGoor	VPI/03-103 US	6802
27916	7590	02/15/2006	EXAMINER	
VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			KOSACK, JOSEPH R	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,022

Applicant(s)

VANGOOR ET AL.

Examiner

Joseph Kosack

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) 1-48, 50, 51 and 56-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49, 52-55, 83 and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/30/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-84 are pending in the instant application.

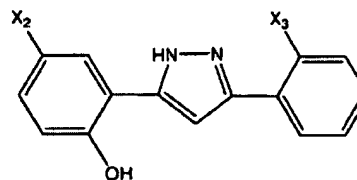
Election/Restrictions

Applicant's election without traverse of Group I (Claims 49 and 52-84) and an election of species of compound IA-6 from page 55 of the specification in the reply filed on February 1, 2006 is acknowledged.

Status of the Claims

Claims 1-84 are pending in the instant application. Claims 1-48, Claim 49 (in part), Claims 50-51, Claims 52-55 (in part), Claims 56-82, and Claims 83-84 (in part) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in the structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Pursuant to Applicant's election of a species, the scope of the invention will be



limited to the following substitutions of the base structure

where:

- X_2 is halogen;
- X_3 is H, halogen, CF_3 , and NO_2 .

As a result of the election and the corresponding scope of the invention defined supra, the remaining subject matter of Claims 49, 52-55, and 83-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as pyrimidinyl, piperidinyl, imidazolyl, pyrrolidinyl, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass 244(+) (diazines), class 546 subclass 184(+) (piperidines), 546 subclass 249(+) (pyridines), etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Priority

The claim to priority of US Serial No. 60/453,978 filed on March 12, 2003 has been acknowledged in the instant application.

Information Disclosure Statement

The Information Disclosure Statement that was received on March 30, 2005 has been considered fully by the examiner.

Claim Objections

Claims 49, 52-55, and 83-84 are objected to for containing elected and non-elected subject matter. The elected subject matter have been identified supra.

Claim 83 objected to because of the following informalities: using codes from the specification to identify compounds. Appropriate correction by replacing the compound codes with either IUPAC chemical names or chemical structures is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 49 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, a pharmaceutical composition comprising elected compounds, a pharmaceutically acceptable carrier, and an additional agent are claimed.

In the art, the addition of therapeutic agents to a pharmaceutical composition consisting of a compound of interest and acceptable pharmaceutical carriers can affect the properties of the compound of interest. Properties affected can include binding constants, rates of diffusion, kinetics of reaction, receptor specificity, etc. The specification provides evidence that pharmaceutical compositions containing elected compounds can contain one of mucolytic agents, a bronchodialator, an anti-biotic, etc, but not any evidence that these combinations have been attempted, or what their affect is on the properties of the elected compounds. Therefore, only the pharmaceutical

Art Unit: 1626

compositions that contain only the elected compounds and a pharmaceutically acceptable carrier meet the written description provision of 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 84 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 84 recites the limitation "a pharmaceutical composition comprising a compound according to any one of claims 40-83." There is insufficient antecedent basis for this limitation in the claim because Claims 40-48 are drawn to a method of modulating ABC transporter activity and Claims 50-51 are drawn to a kit for use in measuring the activity of a ABC transporter or a fragment thereof in a biological sample.

Claim Rejections - 35 USC § 102

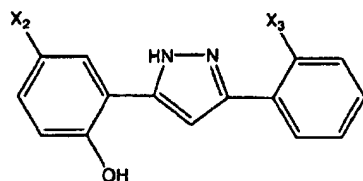
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

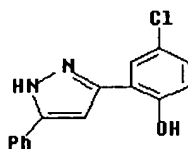
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 49, 55, and 84 rejected under 35 U.S.C. 102(b) as being anticipated by Kästner et al. (DE 41 26 543 A1).

The instant application cites compounds of the formula



where X₂ is halogen; and X₃ is H, halogen, CF₃, and NO₂.



Kästner et al. teach a compound: and its pharmaceutical

composition which reads on the claims when X₂ is halogen and X₃ is hydrogen. See Beispiel 2 on page 7, lines 3-32 and page 6, lines 40-49.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

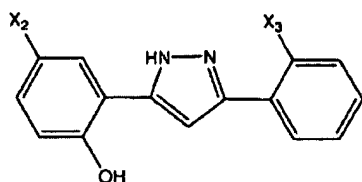
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1626

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

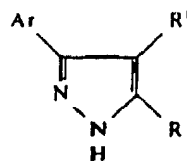
Claims 49, 52-55, and 83-84 rejected under 35 U.S.C. 103(a) as being unpatentable over Kästner et al. (DE 41 26 543 A1).

The instant application cites compounds of the formula



where X_2 is halogen; and X_3 is H, halogen, CF_3 , and NO_2 .

Determination of the scope and content of the prior art (MPEP §2141.01)



Kästner et al. teach a compound of the formula

with substituents

as defined. See page 2, line 60 through page 3, line 6.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Kästner et al. do not teach specifically all compounds which fall into the scope of the instant invention.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Kästner et al. teach generally the compounds of the instant invention, including the elected species when Ar is 2-hydroxyphenyl substituted by Cl, R is phenyl substituted by CF₃ and R¹ is hydrogen. See page 2, line 60 through page 3, line 6. Kästner et al also teaches the pharmaceutical composition comprising the compounds. See page 6, lines 40-49.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to follow the synthetic scheme of Kästner et al. and make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Kästner et al. Kästner et al. teach the use of the synthesized compounds to treat psoriasis. See page 6, lines 28-39.

Thus, the claimed invention as a whole was *prima facie* obviousness over the prior art.

Conclusion

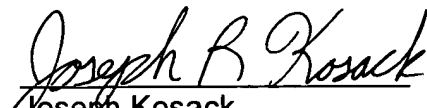
Claims 49, 52-55, and 83-84 are rejected. Claims 49, 52-55, and 83-84 are objected to.

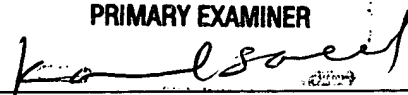
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Joseph Kosack
Patent Examiner
Art Unit 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

for Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626